PATENT COOPERATION TREATY

	From the INTERNATIONAL BUREAU
PCT	То:
NOTIFICATION OF ELECTION (PCT Rule 61.2)	Assistant Commissioner for Patents United States Patent and Trademark Office Box PCT Washington, D.C.20231 ÉTATS-UNIS D'AMÉRIQUE
Date of mailing (day/month/year) 10 March 2000 (10.03.00)	in its capacity as elected Office
International application No. PCT/US99/12959	Applicant's or agent's file reference CM1987Q/VB
International filing date (day/month/year) 11 June 1999 (11.06.99)	Priority date (day/month/year) 26 June 1998 (26.06.98)
Applicant D'ACCHIOLI, Vincenzo et al	
The designated Office is hereby notified of its election made X in the demand filed with the International Preliminary 12 January 200 in a notice effecting later election filed with the International Preliminary	Examining Authority on: 0 (12.01.00)
2. The election X was was not was not made before the expiration of 19 months from the priority da Rule 32.2(b).	te or, where Rule 32 applies, within the time limit under

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

Juan Cruz



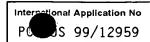
PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference CM1987Q/VB		of Transmittal of International Search Report 220) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/US 99/ 12959	11/06/1999	26/06/1998
Applicant THE PROCTER & GAMBLE COMP	ANY et al.	
according to Article 18. A copy is being tr		thority and is transmitted to the applicant
	of a total of sheets. a copy of each prior art document cited in this	s report.
	international search was carried out on the baless otherwise indicated under this item.	asis of the international application in the
the international search v Authority (Rule 23.1(b)).	vas carried out on the basis of a translation of	the international application furnished to this
was carried out on the basis of the contained in the internation filed together with the internation		nternational application, the international search
	this Authority in computer readble form.	
	bsequently furnished written sequence listing of the s	does not go beyond the disclosure in the
the statement that the inf furnished	ormation recorded in computer readable form	is identical to the written sequence listing has been
	nd unsearchable (See Box I).	
3. Unity of invention is lac	king (see Box II).	
4. With regard to the title,		
the text is approved as su	ubmitted by the applicant.	
X the text has been establis ADHESIVE URINE COLLEC	shed by this Authority to read as follows: TOR	
5. With regard to the abstract,		
the text is approved as su the text has been establis	ubmitted by the applicant. shed, according to Rule 38.2(b), by this Author e date of mailing of this international search re	rity as it appears in Box III. The applicant may, port, submit comments to this Authority.
6. The figure of the drawings to be pub as suggested by the applicant fai because this figure better	icant.	None of the figures.

INTERNATIONAL SEARCH REPORT



A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61F5/443

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) $IPC \ 6 \ A61F$

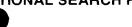
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.	
Х	EP 0 753 290 A (HOLLISTER INC) 15 January 1997 (1997-01-15)	1,3-5, 7-9	
Y	column 7, line 6 - line 41; figures	2,6	
Ϋ́	US 3 759 260 A (NOLAN J ET AL) 18 September 1973 (1973-09-18) column 4, line 47 - line 68; figures 8,9	2	
Υ	US 3 368 561 A (ERICSON RICHARD E ET AL) 13 February 1968 (1968-02-13) column 2, line 30 - line 36; figures 1,2	6	
X	DE 16 16 144 A (DIPPEL) 15 April 1971 (1971-04-15) page 3, line 18 -page 4, line 7; claim 3; figures	1,3,5,9	
	-/		

X Further documents are listed in the continuation of box C.	χ Patent family members are listed in annex.
 Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filling date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filling date but later than the priority date claimed 	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
7 October 1999	Date of mailing of the international search report $14/10/1999$
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Sánchez y Sánchez, J

INTERNATIONAL SEARCH REPORT



International Application No PCOS 99/12959

	PC JS 99/			/12959	
C.(Continua Category °	ation) DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim N	0.	
A .	US 4 784 656 A (CHRISTIAN DELORES J) 15 November 1988 (1988-11-15) column 4, line 59 - line 65; figure 5			1,7,9	
A	GB 1 074 344 A (HOLLISTER) 5 July 1967 (1967-07-05)				
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INTERNATIONAL SEARCH REPORT

on patent family members

International Application No
PC \$ 99/12959

Patent document cited in search report Publication date Patent family member(s) Publication date	
CA 2176782 A 14-01-1 US 3759260 A 18-09-1973 BE 804946 A 16-01-1 CA 1007127 A 22-03-1 DE 2236455 A 29-03-1 DK 135303 B 04-04-1 FR 2153901 A 04-05-1 GB 1379464 A 02-01-1 JP 48037981 A 04-06-1 JP 52027949 B 23-07-1 US 3368561 A 13-02-1968 NONE	1
CA 1007127 A 22-03-1 DE 2236455 A 29-03-1 DK 135303 B 04-04-1 FR 2153901 A 04-05-1 GB 1379464 A 02-01-1 JP 48037981 A 04-06-1 JP 52027949 B 23-07-1 US 3368561 A 13-02-1968 NONE	
US 3368561 A 13-02-1968 NONE	977 973 977 973 975 973 977
DE 1616144 A 15-04-1971 NONE	
US 4784656 A 15-11-1988 NONE	
GB 1074344 A NONE	

PATENT COOPERATION TREATY

PCT

REC'D 18 SEP 2000

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's o	or agent's file refere		See Notification of Transmittal of International OR FURTHER ACTION Preliminary Examination Report (Form PCT/IPEA/416)			
CM19870	Q/VB	PON FORTI	TEN ACTION Prelimina	ary Examination Report (Form 7 0777 EA/410)		
Internationa	application No.	International filin	ng date (day/month/year)	Priority date (day/month/year)		
PCT/US9	9/12959	11/06/1999		26/06/1998		
nternationa A61F5/44		ion (IPC) or national classification	n and IPC			
Applicant						
THE PRO	OCTER & GAM	BLE COMPANY et al.				
1. This ir and is	nternational preli transmitted to th	minary examination report ha	as been prepared by this Ir cle 36.	nternational Preliminary Examining Authority		
2. This F	REPORT consists	s of a total of 7 sheets, include	ding this cover sheet.			
be (s	een amended an ee Rule 70.16 a	accompanied by ANNEXES and are the basis for this report and Section 607 of the Administ of a total of sheets.	t and/or sheets containing	tion, claims and/or drawings which have rectifications made before this Authority the PCT).		
3. This r	⊠ Basis of th	dications relating to the follow	wing items:			
11	☐ Priority					
111	_	olishment of opinion with rega	ard to novelty, inventive ste	ep and industrial applicability		
V	⊠ Reasoned	nity of invention d statement under Article 35(2 and explanations suporting su	2) with regard to novelty, in uch statement	nventive step or industrial applicability;		
VI	_	ocuments cited				
VII	⊠ Certain de					
VIII	⊠ Certain of	oservations on the internation	nal application	·		
Date of sub	mission of the den	nand	Date of completion	n of this report		
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INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/US99/12959

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Claims, No.:

1-9

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.): Description, pages: as originally filed 1-20

as originally filed

Drawings, sheets: 1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages: ☐ the claims, Nos.: ☐ the drawings, sheets:

3.

This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/US99/12959

V. Reasoned stat m nt under Articl 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: No:

Claims 2-4,6

Inventive step (IS)

Yes:

Claims 1,5,7-9

Claims Claims 2-4,6 No:

Industrial applicability (IA)

Yes:

Claims

Claims 1-9 No:

2. Citations and explanations

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re It m V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty and inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents, cited in the international search report:

D1: EP - A - 0 753 290

D2: US - A - 4 784 656

D3: US - A - 3 368 561

D4: DE - A - 16 16 144

V.1. Independant claims

Claim 1 defines a "urine management device".

The document D1 discloses (D1, col. 3, line 33 - col. 4, line 7 and col. 7, lines 38-41) a device comprising all technical features defined in claim 1. The two devices according to D1 and to claim 1 are expressly used for different purpose: D1 relates to a "faecal collector" while claim 1 defines a urine collector. However, this does not imply differences between the technical features of the two devices and therefore the subjectmatter of claim 1 is not new in the sense of Article 33 (2) PCT (see also PCT Guidelines C, IV, 7.6). D4 (p. 3, l. 18- p. 4, l. 4).

Claim 7 relates to a method for placing the urine management device according to claim 1. This method comprises three steps. The two first steps are of common general practice as described in the present application, p. 1, last paragraph. The third step refers to the use of the non-adhesive lobe to manipulate the device. This is not expressly disclosed in document D1. However, it is technically sensible to grasp these non-adhesive lobes which are close to the flange in order to place the device: this step is implicitly disclosed in document D1. Therefore the subject-matter of claim 7 is not new in the sense of Article 33 (2) PCT (see also PCT Guidelines C, IV, 7.2).

In any case, the grasping of such non-adhesive lobe attached to an adhesive releasable element is common practice in the art, in order to achieve precise positioning of the adhesive element on the surface it has to stick to, (see for example document D2).

Document D1 discloses (col. 7, lines 38-59) all steps of the method defined in independant claim 9 for the removal of the device. Hence the subject-matter of claim 9 is not new in the sense of Article 33 (2) PCT. D4 (p. 3, l. 18- p. 4, l. 4).

V.2. Dependant claims depending on claim 1

Document D1, considered as the closest prior art, describes a device with only one lobe while claim 2 states that at least two lobes are comprised in the urine management device. This multiplicity of lobes achieves the following technical effects: grasping of the lobes by the caretaker with the two hands and some choice in the position of its hand(s) relative to the device and the patient when placing or removing the device. Several lobes have already been employed to achieve such effects in a similar device, see document D2, col. 6, lines 6-14. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a urine or faecal collector according to document D1, thereby arriving at a urine management device according to claim 2. The subjectmatter of claim 2 does not, therefore, seem to involve an inventive step (Article 33(3) PCT).

Claim 3 specifies the position of the lobe relative to the flange of the urine management device (in case there is only one lobe). Document D1 does not give any precision about this position. When interpreting the term "upward" in the sense given p. 14 of the description (see here above, item VIII), this position is more easily accessible by the caretaker when removing the device from the uro-genital area of a wearer, due to the room taken by its legs. The choice of this position comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance. Consequently, the subject-matter of claim 3 appears to lack an inventive step (Article 33(3) PCT).

Claim 4 specifies the positions of the lobes relative to the longitudinal axis of the flange (see item VIII bellow), in case there are at least two lobes. Such positions allow a more precise positioning of the device by the caretaker when placing the device in the urogenital area of a wearer, since the flange has to be curved around its longitudinal axis in order to fit the wearer. The choice of these positions comes within the scope of the customary practice followed by persons skilled in the art, because the advantages thus

achieved can be readily contemplated in advance. Consequently, the subject-matter of claim 3 appears to lack an inventive step (Article 33(3) PCT).

Document D1 also describes the release means defined in **claim 5**. Therefore the features of claim 5 are not new within the meaning of Article 33 (2) PCT.

The additional features of the release means as defined in **claim 6** is known from document D3 and employed therein to achieve the same effect as in the present application: to facilitate the removal of the release means. Hence it would obvious to the person skilled in the art, namely when the same result is to be achieved, to combine these features known form D3 with the device according to D1. Therefore the subject-matter of claim 6 does not involve an inventive step (Article 33(3) PCT).

V.3. Dependant claim 8, depending on claim 7

Claim 8 relates to an additional step, for placing a urine management device, which is needed when the device comprises the release means defined in claim 5. Such device with release means is known from D1 and this additional step is described therein (D1, col. 7, 14-37). Therefore, the subject-matter of **claim 8** is not new (Article 33 (2) PCT).

V.4. Industrial application

Industrial application is self-evident. Thus, the claims appear also to fulfil the requirements of Article 33 (4) PCT.

Re Item VII

Certain defects in the international application

VII.1. Dependency of claim 8

It seems that claim 8 should relate to the method of claim 7 (rather than "the method of claim 8").

VII.2. Two part form

Independent claims 1, 7 and 9 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule

6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

VII.3. Acknowledgement of background art documents

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application concerning clarity

VIII.1. The term "upward" used in claim 3 is defined in the description p. 14 as having a particular meaning within the application and the subject-matter of claim 3 is therefore not clear from the wording of the claim alone (Rule 10.1 (e) PCT and PCT Guidelines C, III, 4.2). In the present International Report, the subject-matter of claim 3 has been interpreted in the light of the definition of upward given p. 14.

VIII.2. In claim 4, the positions of the lobes relative to the "longitudinal axis" of the device is defined, while these positions are defined relative to the longitudinal axis of the flange in the description. Hence the subject-matter of claim 4 lacks consistency with the description (PCT Guidelines C, III, 4.3). In this application these two axes are one and the same but it is not the case in some prior art documents (see for example D1 in which the longitudinal axis of the device extends from the element 13 to the centre of the flange). Therefore claim 4 should clearly refer to the longitudinal axis of the flange. In the f present International Report, claim 4 has been examined as defining the position of the lobes relative to the longitudinal axis of the flange, as in the description.